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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/684,016
Filing Date: October 10, 2000
Appellant(s): KOVALIC ET AL.

Lanrence M. Lavin, Jr. and David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the amended appeal brief filed 12/22/2006 appealing from the Office action mailed 6/17/2003.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

1. In re Fisher, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005)
2. U.S. Appln. No. 09/619,643, BPAI Appeal No. 2002-2046
3. U.S. Appln. No. 09/654,617, BPAI Appeal No. 2003-1744
4. U.S. Appln. No. 09/620,392, BPAI Appeal No. 2003-1746
5. U.S. Appln. No. 09/540,232, BPAI Appeal No. 2003-1137
6. U.S. Appln. No. 09/440,687, BPAI Appeal No. 2003-1504
7. U.S. Appln. No. 09/565,240, BPAI Appeal No. 2003-1135
8. U.S. Appln. No. 09/540,215, BPAI Appeal No. 2003-0996
9. U.S. Appln. No. 09/552,087, BPAI Appeal No. 2004-1772
10. U.S. Appln. No. 09/206,040, BPAI Appeal No. 2002-0078

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of the Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) Claims 11-16 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of these nucleic acids are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds can be used in isolating more genes and homologs from plants, such as maize, etc. (see pages 37-38). All these possible uses are generic to any expressed nucleic acid sequences from plants. As a matter of fact, the specification summarized pretty much the modern biotechnology in general, but never connects

any of the specifically elected sequence to any particular or specific utility. This wishlist-like desire for a utility for the claimed sequences seems to fall short of a readily available utility.

Further, the claimed nucleic acid is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, in the aforementioned uses in isolating new genes in plants. Further research is clearly needed to isolate the gene, to isolated the protein, if any, encoded by the gene, and to study the function/activity of the protein in order to find uses for that gene and that protein. This apparent need for such research indicates that the nucleic acid is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context for use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds.

Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the elected nucleic acid compound.

(b) Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention lacks patentable utility due to its not being supported by a specific,

substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(c) Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 11-15 are drawn to nucleic acids comprising the sequence of SEQ ID NO:48411, which is a fragment of an open reading frame. The instant specification only discloses species, i.e. the DNA sequence of SEQ ID NO:48411. However, given the broad scope of the claims, they are drawn to a genus: any polynucleotide or nucleic acid that minimally contains the sequence of SEQ ID NO:48411, or a fragment thereof, including any full length gene which contain the sequence, any fusion constructs, any RNAs or cDNAs, etc. There is substantial variability among the species of polynucleotides or nucleic acids encompassed within the scope of the claims because the claimed SEQ ID NO is only a fragment of any full-length gene or cDNA species, or any vector due to the use of the open language "comprising". Since the claimed genus encompasses species yet to be discovered, DNA constructs that encode fusion proteins, etc., the mere disclosure of a species: sequence of the claimed SEQ ID NO, does not provide an adequate description of the claimed genus. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs or RNAs encompassed in claims 11-15, which comprise the sequence of the claimed SEQ ID NO.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:48411, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotide/nucleic acid, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, in the instant application, only SEQ ID NO:48411, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (See page 1115).

(d) Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 14 is amended to recite "a substantially purified nucleic acid having between 90% and 100% sequence identity with base pairs 1 through 123 of SEQ ID NO:48411 and a complete complement thereof" in the amendment filed 8/8/02. However, while the specification discloses the entire sequence of SEQ ID NO:48411, it does not specifically describe the newly added limitation of "base pairs 1 through 123 of SEQ ID NO:48411," which is thus deemed new matter.

(e) Claim 13 is rejected under 35 U.S.C. § 102(b) as being anticipated by Mahairas et al. (GenEmbl Acc. No. AQ451805, 4/21/1999).

The amended claim 13 is interpreted as claiming a nucleic acid comprising a fragment of about 30 to about 50 nucleotides long but the claim does not indicate this fragment of 30-50 bps is entirely from SEQ ID NO:48411. Thus this fragment can be any nucleic acid fragment of about 30-50 bps long. The claim also requires that this fragment exhibits complete complementary to a fragment of SEQ ID NO:48411.

Mahairas et al. disclose a purified nucleic acid molecule comprising a fragment of at least 30 nucleotides that comprises 20 contiguous nucleotides that is 100% complementary with a fragment of the instant SEQ ID NO:48411.

Absent a definition for the term "fragment" of SEQ ID NO:48411, one or more nucleotides are considered as fragment. Thus, nucleotides 98-118 of SEQ ID NO:48411 is a fragment of SEQ ID NO:48411. The nucleic acid molecule disclosed by Mahairas et al. contains a fragment of around 30 and that fragment is completely complementary to the fragment of nucleotides 98-118 of SEQ ID NO:48411 as shown in the sequence alignment provided to applicants in the previous Office action. Complete complementarity here is interpreted as being that every nucleotide of the fragment of nucleotides 98-118 of SEQ ID NO:48411 is matched by a nucleotide from the fragment of the nucleic acid molecule disclosed by Mahairas et al.

(10) Response to Argument

Appellant's arguments are addressed *seriatum*.

It should be pointed out that this application is analogous and related to US applications 09/654,617 (BPAI Appeal NO. 2003-1744) and 09/620,392 (BPAI Appeal NO. 2003-1746) (both applications have also been examined by the present examiner). For both appeals, the Board has affirmed the rejections of claims under 35 USC 101 for lack of utility and under 35 USC 112, first paragraph for lack of enablement.

Sections 8A and 8B (pages 4-14 of the brief)

In the summary of appellants' position, Appellants assert that the claimed invention meets the utility and enablement requirements because they have disclosed "nucleic acid molecules which, in their current form provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism (page 5 of the brief)." The examiner does not agree that the nucleic acid molecules provide any specific benefit to the public in their current form but rather require further experimentation to determine whether such a benefit can be found. Appellants also assert that the specification has provided an adequate description for nucleic acid molecules "comprising" the sequence of SEQ ID NO:48411 because they have disclosed SEQ ID NO:48411 (page 5 of the brief)." The examiner does not agree that the structure of SEQ ID NO:48411 provides adequate description for claims encompassing the nucleic acid for the gene encoding full length proteins. Neither the structural and functional properties of any gene (including introns and other non-coding sequence) comprising SEQ ID NO:48411, nor the structural and functional properties of any protein or fragment thereof encoded by a nucleotide sequence comprising SEQ ID NO:48411are disclosed in the specification.

The Examiner agrees that the "threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit," with the proviso that the benefit be "identifiable" in the original disclosure either as a specific assertion or being readily apparent from the disclosure (i.e. well established). The Examiner also agrees "the invention must have specific, i.e. not vague or unknown benefit" and "must provide a real world, i.e. practical or substantial, benefit." Whether the instant application has met this burden is the subject of this appeal.

Appellant argues that the claimed nucleic acid molecules can be used to detect the level of mRNA in a sample and argues in footnote #1 (page 8 of the brief) that knowing that the gene corresponding to the claimed nucleic acid is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. This is not found persuasive because without knowing the function/activity of the gene or the polypeptide encoded thereby and the associations, if any, between the level of the mRNA with any specific conditions and/or specific tissues and the practical significance of the expression level, merely knowing the gene is expressed would not render any practical utilities. It would clearly require further research to determine any such associations between the level of the mRNA with any specific conditions and/or specific tissues in order to determine any practical utilities.

to detect the presence and/or identity of polymorphisms, and as a molecular marker. The Examiner maintains that further research is required for such uses.

Use as antisense inhibitors would require further experimentation to determine the target of inhibition. These targets are not disclosed in the specification. Appellants' arguments with

respect to cell-based assays are not persuasive. MPEP 2107 states, "An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring." The instant specification sets forth no such correlation for any condition. It is noted that this section of the MPEP goes on to state that:

On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;

(B) A method of treating an unspecified disease or condition;

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;

(D) A method of making a material that itself has no specific, substantial, and credible utility; and

(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

All of these situations more closely match appellant's disclosed uses. They do not define substantial utilities.

Foot note 3 on page 7 of the brief discusses uses of microarrays. Appellant is not claiming microarrays or collections of nucleotides and the specification does not associate the claimed sequence with any trait of interest. Contrary to appellant's assertions, further

experimentation is required to identify a "real world use." A negative result to such a screen tells what the nucleic acid is not and cannot be used for. A positive result to such a screen requires further experimentation to determine what, if anything, such a change means. It is not an immediate benefit except in the sense to indicate that further research may yield a "real world use."

Applicant further argues that the claimed nucleic acid can be used to detect the presence or absence of polymorphisms, and argues that this is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas, and present an example in footnote #3 (page 9).

This is not found persuasive.

MPEP 2107 in discussing research tools sets forth the following:

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

Again, further experimentation is required to determine and confirm any of the uses set forth by appellant for the claimed nucleotide sequences.

The gas chromatograph example set forth by appellant, particularly as discussed in Footnote 3 on page 9, is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated, and calibrated to ensure accurate results. Those skilled in the art use gas chromatographs to analyze both known and unknown compounds. When the compound is unknown, the results obtained are compared to results for known compounds, e.g. standards. Appellants did not design the claimed nucleotide sequences for any particular purpose. They merely isolated them. They have not tested, evaluated, or calibrated the claimed nucleotide sequence for any particular use. Sampling for the presence or absence of chlorine in a crude oil sample is not analogous to the present situation. The presence or absence of chlorine in a crude oil sample has a known meaning based upon prior research. Absent establishment of this association between presence of chlorine and destruction of catalyst, the presence or absence of chlorine in a sample would not provide any useful information to the refinery manager. Likewise, the presence or absence of the claimed nucleotide sequence in a sample (or polymorphisms thereof) has no meaning absent some association. Further experimentation is required to determine what, if any, that meaning or association might be.

In addition, this gas chromatograph analogy fails to address Appellants' own definition of the term polymorphism. The specification (page 40, lines 6-7) defines "polymorphism" as "a variation or difference in the sequence of the gene or its flanking regions that arises in some members of a species." It follows from this definition that if there is no "variation or difference in the sequence of the gene or its flanking regions" among "members of a species," then no polymorphism exists, i.e. a polymorphism is absent, in this region of the genome. A "polymorphism" is a collective concept defined by at least two variants (or alleles) found within members of a species collectively. Thus, one detects the *presence* of a polymorphism by analyzing multiple members of the species, i.e. analyzing a population. While one can detect the absence (or presence) of a specific allele of the polymorphism in a specific individual member of the species, one cannot detect the *absence* of a polymorphism *per se* based on one individual alone. The absence of a particular allele necessarily means that a different allele is present. The specification fails to disclose a specific and substantial utility for the claimed invention in the capacity of detecting polymorphisms, because it does not disclose whether the claimed nucleic acid molecules can, in fact, be used to detect any polymorphism whatsoever. Thus, the specification leaves open the possibility that there may be no polymorphism to detect. With respect to the gas chromatograph analogy, one can only detect the absence of a compound, such as chlorine, in a sample, *if* it was already known that chlorine could, in fact, be detected by the gas chromatograph were it present in the sample.

The specification generally teaches using the claimed polynucleotides to identify a polymorphism, but fails to teach that a polymorphism could in fact be detected, or a specific polymorphism that could be detected. The specification generally teaches using a

polymorphism, detectable with the claimed nucleic acid molecules, as a molecular marker for a linked trait of interest, but fails to teach either the polymorphism or the trait of interest. The court in *Kirk* (at page 53) held:

> *We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.*

The specification (page 40, lines 6-7) defines "polymorphism" as "a variation or difference in the sequence of the gene or its flanking regions that arises in some members of a species" (emphasis added). The following pages of the specification discuss various types of sequence polymorphisms and how they are detected. It is noted that on page 11, lines 11-12, the specification states, "By correlating the presence or absence of it [a polymorphism] in a plant with the presence or absence of a phenotype...". Thus, the specification acknowledges that further analysis is required to determine a use for a polymorphism even assuming one is found. A change of phenotype and correlation with phenotype must be found.

Even to determine whether a polymorphism exists at a specific chromosomal location requires hybridization to at least two individual chromosomes, and generally involves analyzing genomic DNA from multiple members of a species; the specification discloses no such analysis.

The specification fails to disclose: 1) whether the claimed nucleic acid molecule can in fact detect a polymorphism, or even whether such a polymorphism exists; and 2) at least one specific example of at least one of the types of polymorphisms described in the specification. The specification does not disclose any utility in this context for a nucleic acid molecule or EST that cannot detect a polymorphism. Therefore, using the claimed invention to first determine whether or not the claimed nucleic acid molecule can, in fact, detect a polymorphism *is* to determine whether or not the claimed invention has a utility that requires detecting a polymorphism, i.e. it is "use testing" and not substantial. Since the specification fails to identify even one specific polymorphism that can be detected with the claimed nucleic acid molecule, the specification fails to show any specific correspondence between the disclosed general utility and the claimed subject matter, regardless of any specific application requiring detection of polymorphisms.

Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* (pages 10-11) of the brief) in support of their position that utility has been established. However, this decision is with respect to a mechanical device and not a laboratory reagent or research tool. Furthermore, applicant mischaracterizes the findings in this decision. This decision concerned claim interpretation and the CAFC found that the district court had erred in their interpretation of what the claim embraced and thus what was required to establish utility. The claimed device was found to fulfill the stated objective of mounting a stylus by the CAFC. These facts do not correspond to the instant specification

While the specification teaches that the claimed nucleic acid molecules "*may be used* to isolate nucleic acid molecules from other cereals", etc. (emphasis added), the specification does

not indicate that any such nucleic acid molecules *had been* obtained, nor does it describe any characteristics possessed by such nucleic acid molecules. As to whether such molecules could, in fact, be obtained, the Office can neither prove nor disprove the assertion because the Office does not have laboratory facilities. At the time the application had been filed, future experimentation on the part of one skilled in the art would have been required to determine which, if any, other plant species contained nucleic acid molecules that could have been obtained using the claimed invention, and under what experimental conditions. Furthermore, since further research is needed to determine what, if any, real world utility the "nucleic acid molecules from other cereals" may have, the use of the claimed nucleic acid for obtaining the "nucleic acid molecules from other cereals" falls short of a substantial utility.

With respect to using the claimed nucleic acid molecules to initiate a chromosome walk, such as to isolate a promoter of the corresponding gene, the specification fails to disclose any characteristics of the corresponding promoter, or any other promoter within "chromosome walking" distance; neither structural characteristics, by which the promoter might be identified, nor functional characteristics, by which a specific and substantial use for the promoter might be determined.

In this context, the claimed invention does not compare to a golf club, because one knows what a golf ball is and how to use the golf club to hit it, whereas the specification does not disclose or describe with particularity any known useful nucleic acid molecule that can be obtained, such as the corresponding promoter - it simply invites the skilled artisan to provide such information by further experimentation.

Even if assuming *arguendo* that the corresponding promoter exists is no more guidance for its isolation, and eventual use, than knowing that a haystack contains a needle - at least one is presumed to know what the needle looks like. Also, the specification does not disclose the distance or direction one has to walk on a chromosome from the corresponding location to reach the corresponding promoter. Thus, starting the walk at the corresponding chromosomal location is no more help in identifying the promoter than is picking a specific location in a haystack to start looking for a needle when one does not know where the needle is relative to the starting location. Initiation of a chromosome walk at the corresponding chromosomal location is considered non-specific because any EST would serve the purpose for isolating an uncharacterized promoter, since any chromosomal location is expected to be linked to a promoter. The specification fails to disclose sufficient characteristics of the corresponding promoter, such as its sequence or precise location relative to the genomic location corresponding to the claimed nucleic acid molecule, to inform one of what the corresponding promoter is or when it has been isolated. For example, a nucleotide sequence is identified during the chromosome walk as a putative promoter by sequence analysis, is then subcloned into operable linkage with a reporter gene and transfected into an appropriate cell, but found not to express the reporter gene in the cells. This result could mean the putative promoter: is not truly a promoter, i.e. a false positive; is not the corresponding promoter; or is incomplete, i.e. lacked additional sequence elements required for promoter activity in the seed pod cells. Substantial utility means that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate* benefit to the public," *Nelson v. Bowler*, 206 USPQ2d 881, 883 (CCPA 1980) (emphasis added). Since the specification does not describe the corresponding promoter, or any

other specific nucleic acid molecule, sufficient to inform one skilled in the art that it has been isolated, there can be no "*immediate* benefit to the public" in using the claimed nucleic acid molecule in this capacity; "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion," *Brenner* at page 696.

With respect to the "real world" value of ESTs in general (brief, pages11-12), it is asserted that there is "no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed 'real world' value to such nucleic acid molecules." See page 12, second full paragraph. It is unclear as to what evidence Appellants are alluding. The evidence supplied by Appellants shows that a multimillion dollar industry has arisen surrounding buying and selling EST databases and clones, not that anyone in this industry has bought or sold the claimed subject matter. It is noted that simply because a product, such as an EST sequence database or clone library, is bought and sold does not mean it has patentable utility.

With respect to credibility (page 13 of the brief), appellant is reminded that in order to meet the requirements of 35 USC 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of well established utility, which would presume that the utility was credible). The claims have been rejected because 1) the specification fails to disclose at least one utility that is both specific and substantial, and 2) no convincing evidence has been presented to show that an EST, for which only its nucleotide sequence and source have been disclosed, has a well established utility.

The brief does not appear to directly argue for a well established utility for the claimed invention; however, the arguments concerning the commercial value of ESTs in general (brief, pages 11-12) may implicitly be directed to a well established utility for any EST in general, and

the claimed nucleic acid molecules in particular. However, such evidence is not relevant to 35 USC 101.

Section 8C (page 14 of the brief)

The Examiner maintains that the uses asserted for the claimed invention are methods where the claimed invention is, itself, an object of scientific study, e.g. to determine whether the corresponding genomic DNA in a species contains a polymorphism that can be detected with the claimed invention. The specification cannot enable or tell how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. The Examiner maintains that there is no patentable utility for the claimed invention for the reasons set forth above and thus the claims are not enabled.

Section 8D (pages 14-18)

The issue is whether Applicant was in possession of the genus being claimed. This genus is not restricted to any particular disclosed subgenus or species, such as vectors comprising SEQ ID NO: 48411 as an insert. The only nucleic acid molecules described by complete structure are those consisting of SEQ ID NO: 48411. The only nucleic acid molecules comprising of SEQ ID NO: 48411 described in the specification by other characteristics are generic vectors comprising the sequence of SEQ ID NO: 48411.

While it is acknowledged that Appellant need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire

genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that comprises SEQ ID NO: 48411 and additional sequences of any size and sequence, not just vector backbones. Clearly, at the time of filing, Appellant was not in possession of genomic materials that contain the common EST fragment, which are embraced by the open-ended claims. The specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers for detection of SEQ ID NO: 48411 in a target sequence, and all disclosed uses for the claimed nucleic acid molecules are fundamentally as probes or primers, at least in some aspect. The specification does not disclose encoding sequences or open reading frames (ORFs).

With respect to full length mRNAs, cDNAs and genomic sequences, one skilled in the art would reasonably conclude that the claims embrace these nucleic acid molecules, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising SEQ ID NO: 48411 and no other indication that would suggest Appellant possessed them. This particular subgenus embraced by the claims has a disclosed potential utility not possessed by those members of the claimed genus useful only in hybridization. Full length mRNAs, cDNAs and genomic sequences (genes) would encode the corresponding protein(s).

A fundamental issue here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Appellants and the Examiner disagree is whether the disclosure of a partial sequence of otherwise uncharacterized nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus

based solely on the description of the partial sequence, where the broad genus embraces the uncharacterized nucleic acid molecules by default. The subgenus of uncharacterized nucleic acid molecules that encode any corresponding protein is explicitly alluded to in the specification, and disclosed as possessing an additional use *not* possessed by any other members of the broad genus being claimed, i.e. encoding the protein. The specification fails to provide any structural or functional characteristic for these desired nucleic acid molecules, which encode the protein, that would distinguish them from the other members of the genus, which simply comprise SEQ ID NO: 48411 as the sole distinguishing feature. As stated in *University of California v. Eli Lilly and Co.* at page 1404:

> *An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.*

That Appellants' claims embrace nucleic acid molecules that encode a corresponding protein, whatever it may be, is clearly evident from the claim language chosen. The Court in *University of California v. Eli Lilly and Co.*, at page 1405, further noted regarding generic claims:

> *A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or]*

chemical name," of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe , 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .").

In the instant case, the only species specifically enumerated is the nucleic acid molecule of SEQ ID NO: 48411 itself. The specific embodiments that in addition to SEQ ID NO: 48411 include nucleic acids that will allow the corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence has not been disclosed. Clearly, the specification would not show one skilled in the art that these desired sub-combinations were possessed by Appellant, and thus the embracing genus was also not possessed.

Section 8E (pages 18-19 of the brief)

Upon reconsideration, the new matter rejection is hereby withdrawn.

Section 8F

The issue at hand is whether the nucleic acid disclosed by Mahairas et al. anticipated the claimed nucleic acid of claim 13.

The claim is copied below:

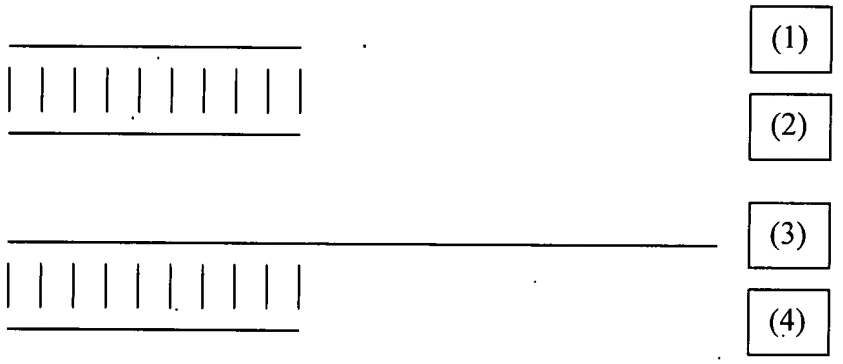
13. A substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues, wherein said

fragment nucleic acid molecule exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof.

The claimed nucleic acid is dissected as a purified nucleic acid molecule (A) comprising a fragment nucleic acid (B) having about 30-50 nucleotide residues, wherein (B) exhibits complete complementarity to a fragment (C) of a second nucleic acid molecule (D) having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof.

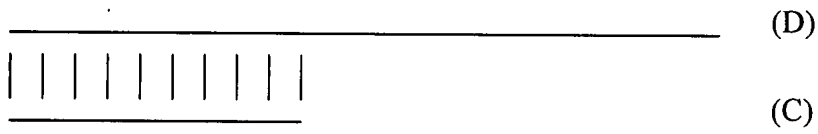
It should be particularly pointed out that the claim does not specify the sequence of (B) but only requires that (1) it is about 30-50 nucleotides long and it exhibits complete complementarity to (C), which is part of (D) that has the sequence of SEQ ID NO: 48411 or a complete complement thereof, and that there is no length requirement for (C).

It also should be pointed out that absent a definition to indicate otherwise, complete complementarity between two sequences is interpreted to include at least the following two situations, where the two sequences exhibit complete complementarity:



It is perfectly clear that nucleic acid (1) and (2) exhibit completely complementarity. In the case of nucleic acids (3) and (4), because the complete sequence of (4) is entirely complementary to sequence (3), it is interpreted that (3) exhibit complete complementarity to (4).

Mahairas disclose a purified nucleic acid molecule that is 349 bps long. This is interpreted as reading on the (A) of the claimed nucleic acid. Any part of the molecule is a fragment thereof. Take the fragment including nucleotides 39-69, which is 31 bps long. This is interpreted as reading on (B) of the claimed nucleic acid, which is at least 30 bps long. This fragment comprises a portion of 20 consecutive nucleotides (nucleotides 49-69) that is completely complementary with a fragment of SEQ ID NO:48411 (nucleotides 98-118), which is also 20 bps long. This 20 base-pair-long fragment of SEQ ID NO:48411 is interpreted as (C). Thus, the complementarity relationship between (B) and (C) is as follows:



Clearly this is exactly the same relationship as that shown between nucleic acids (3) and (4) above, which is interpreted as exhibiting complete complementarity with each other.

Therefore, the claimed invention of claim 13 is anticipated by Mahairas et al.

For the above reasons, it is believed that the rejections other than those withdrawn by the Examiner in this Answer are proper and should be sustained.

Respectfully submitted,

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April 27, 2007

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